



OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

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October 4, 1999

Dockets Management Branch (HFA09-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Reference: Docket # 99D09-2013. *Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics.*

To Whom It May Concern:

America's Blood Centers appreciates the opportunity to comment on the FDA's draft guidance document: *Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics.*

Many blood collection organizations have entered into agreements with other blood collection organizations to share the manufacturing of blood and blood components. The most common arrangement is where one facility collects, processes, labels and distributes all components and the other blood collection facility tests those same blood components. Both organizations are fully licensed to manufacture the blood products, but economically, it is more feasible for one facility to perform all the testing. While the responsibilities seem to most closely fit description of "shared manufacturing," the definition offered in the draft guidance indicates that both manufacturers are only licensed for part of the process, not all.

ABC seeks clarification of the appropriate category of manufacturing arrangement for a situation in which one licensed blood center performs infectious disease testing for another licensed blood center.

Section IV. Divided Manufacturing Arrangements. ABC does not believe that cooperative manufacturing arrangements between two licensed blood centers fall into this category. We would appreciate clarification that this is a correct interpretation of CBER's intent.

Section V. Shared Manufacturing Arrangements. Paragraph # 1 states that "Shared manufacturing is an arrangement in which two or more manufacturers are licensed and responsible for specific, different aspects of the manufacture of a product but neither is licensed for all aspects of the product manufacturing. . . Critical manufacturing steps. . . that FDA has considered adequate for separate licensure include . . . required infectious disease testing of blood and blood components. . ."

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This implies that the blood center that is providing required infectious disease testing **cannot** be licensed for all aspects of the product. We **recommend** that the definition of shared manufacturing be broadened to include two fully-licensed manufacturers.

Section VI. Contract Manufacturing Arrangements. Paragraph #1 states: "For the purposes of this document, contract manufacturing refers to a situation in which a license applicant establishes a contract with another entity(ies) to perform some or all of the manufacture of a product as a service to the license applicant."

Please clarify that under the contract manufacturing arrangement scenario, both the license applicant and the contractor may hold an FDA license.

Paragraph #2 states: "Because the applicant assumes responsibility for compliance of the contract site...the applicant should have access to...information from the contract site necessary to assure safety, purity and potency of the product. The applicant should be fully informed of all deviations, complaints and adverse events, as well as the results of all tests and investigations possibly impacting the product."

We recommend that this section be modified to specify that requirements for a contractor to provide information to the license applicant be limited to information that directly affects the services provided (e.g., testing)-and not to information on its other FDA-regulated activities.

Requiring unlimited access to compliance information does not reflect the current relationship between some collecting facilities and their contract-testing facility. Deviations, complaints and adverse events other than those that directly affect testing for the collecting facility are often considered proprietary information by blood bank establishments, and as such are not shared with other centers. The contract between the collecting facility and the contract facility generally allows for exchange of information regarding the results of proficiency testing, reports resulting from inspections by the FDA or American Association of Blood Banks, and deviation reports directly related to the collecting facility test runs.

Paragraph #8. We agree with the statement in paragraph #8 that states: "Because the contract facilities are considered to be under the auspices of the license holder, specific identification of the contractor in the product labeling is not required."

Clarification:

It would be helpful if the guidance clarified the following:

- The benefits to the end user of dual labeling under a shared manufacturing arrangement
- How the guidance applies to transfusion facilities that modify and relabel a blood product purchased from a licensed blood center

If you would like to discuss the above questions further I can be reached at (302) 737-8405, extension 767.

Sincerely,

Heather Russell / H.

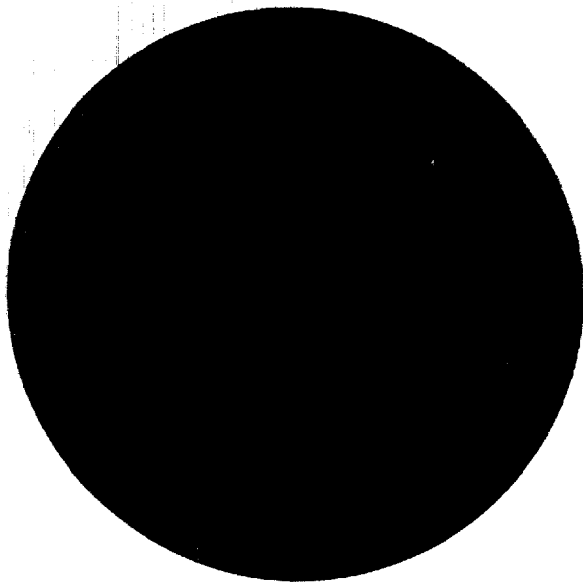
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